Ackermann

EC-DECLARATION OF CONFORMITY

We the

Ackermann Instrumente GmbH

Street: Eisenbahnstrasse 65-67
ZIP: 78604
City: Rietheim-Weilheim
Ctry.: Germany

Phone: +49 (0)7461 966 17 0
Fax: +49 (0)7461 966 17 70
E-Mail: info@ackermannsurgical.com

issue as the manufacturer the present Declaration of Conformity on our sole responsibility and herewith declare self-dependently that the device meet the Essential Requirements as defined in Annex I MDD 93/42/EEC.

This Declaration of Conformity is issued according to Annex II Council Directive 93/42/EEC for Medical Devices (for class IIa and IIb devices) excluding section 4.

Device Name:	Ackermann Fusion Insufflator
Item #:	16-2045
UMDNS:	16-849
GMDN:	36747
Classification:	IIa, according to 93/42/EEC, Annex IX
Notified Body:	KIWA Belgelendirme Hizmetleri A.S. ITOSB 9. Cad. No: 15 Tepeören, Tuzla Istanbul, Turkey Notified Body Identification Number: CE 1984

Conformity Assessment has been performed under supervision of the Notified Body specified above. The devices may, therefore, be placed into market labelled with

CE 1984

This Declaration is valid for all devices listed in the Device List below until February 18, 2024.

Digitally signed by Bunic Gheorghe
Date: 2025.03.24 21:48:53 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

2020-05-24
PETER GRASSL
CEO

This declaration loses all validity if the Ackermann Instrumente GmbH performs a product change which affects the Conformance to the Essential Requirements or any other alteration not approved.